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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1306]

**Draft Guidance for Industry on the Content and Format of the Adverse Reactions
Section of Labeling for Human Prescription Drugs and Biologics; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics." The agency has initiated a comprehensive effort to improve the content and format of prescription drug labeling. This draft guidance is the first in a series of guidance documents on the content and format of individual labeling sections. FDA intends to carefully coordinate development and implementation of these various labeling initiatives to minimize the potential burden for manufacturers and other affected parties.

DATES: Submit written comments on the draft guidance by *[insert date 90 days after date of publication in Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or at <http://www.fda.gov/cber/guidelines.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX, or Voice Information cd97117

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System at 800-835-4709. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Janet M. Jones, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6758, or

Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6190, e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION: As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. FDA is developing and intends to publish a proposed rule to revise the overall format of prescription drug labeling. It will propose reordering the sections of the labeling, based on the importance of the information to practitioners, and the frequency with which practitioners refer to a section and creating a “highlights” section and an index.

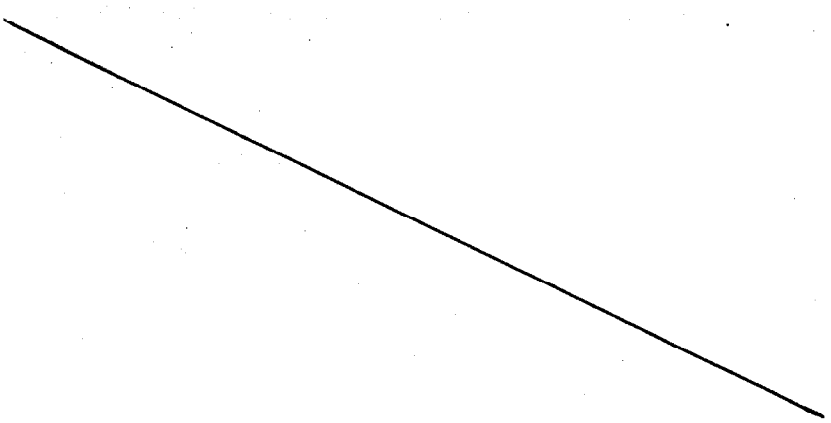
FDA also is working on a proposed rule to revise the current requirements for the pregnancy subsection of labeling (see 62 FR 41061, July 31, 1997, announcing 21 CFR part 15 hearing to discuss the category requirements, and 64 FR 23340, April 30, 1999, announcing a public advisory committee meeting to discuss possible changes to pregnancy labeling).

In addition, FDA is developing guidance documents that focus on the content of certain labeling sections. The draft guidance on “Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics” provides guidance on, among other things, criteria for including adverse reactions in labeling, presentation of adverse reactions in a table, and organization of the section. This section exists in the current labeling and is expected to continue to exist when the new format for prescription drug labeling is proposed.

At this time, FDA also is developing guidances for the Clinical Pharmacology, Clinical Studies, and Warnings/Precautions sections. The agency expects to publish these draft guidances for comment in the coming months. To date, the agency has focused its efforts on these sections because they typically contain large amounts of important and complex information and there have been significant variations in their format and content across different medical products. Guidances for other labeling sections may be developed later.

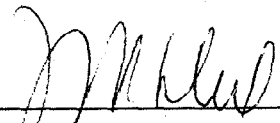
This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the content and format of the adverse reactions section of labeling for human prescription drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found



in the brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/14/00
June 14, 2000



Margaret M. Dotzel
Associate Commissioner for Policy

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Jen Windsor

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